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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/561,752 | 01/26/2006 | Anthony Bruce Pike | 16-978P/US | 1633 |
| 26294 7590 04/13/2009 TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700 CLEVEVLAND, OH 44114 | | | | |
| EXAMINER NICHOLSON, KERI JESSICA | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3772 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 04/13/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/561,752

Applicant(s)

PIKE, ANTHONY BRUCE

Examiner

KERI J. NICHOLSON

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2009.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9,12 and 14-26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,2,4-9,12 and 14-26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 07 July 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/11/2008 & 3/27/2009
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

This is the second Office action based on non-provisional application 10/561,752 filed January 26, 2006 for the amendments to the specification and claims filed July 7, 2008. An information disclosure statement was filed October 8, 2008 and two other information disclosure statements were filed March 27, 2009; all were considered by the examiner April 9, 2009. A response to the Requirement for Information mailed November 14, 2008 was filed March 27, 2009 and also considered by the examiner April 9, 2009. Claims 23-26 have been added; claims 1, 2, 4-9, 12, and 14-26 are currently pending.

Information Disclosure Statement

1. The information disclosure statement filed July 11, 2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.
2. The information disclosure statement filed March 27, 2009 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Abstract

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the use of the implied phrase "is disclosed". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 17 fails to further limit the subject matter of a previous claim since it appears Applicant is attempting to broaden the claim. Since claim 17 is dependent from claim 16, by nature it must include all of the limitations of claim 16 including the toe.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(f) he did not himself invent the subject matter sought to be patented.

8. Claims 1, 2, 4-7, 12, 14, and 15 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. As best can be understood, the medical protection sheeting as claimed by Applicant is nothing more than a sheet of material providing the claimed properties that are found in materials made by DuPont (470T743, 350T749, 98Wext/4) as disclosed by Applicant's specification (page 2, lines 22-29; page 3, lines 15-19). Further, a product guide sheet published by DuPont on February 21, 2003, indicates that both 470T742 and 350T749 material were known and commercially available prior to Applicant's filing date (see attached DuPont Airbag Fibers). Therefore, the invention encompassed by Applicant's claims are directed to the materials made by DuPont rather than an invention made by the applicant.

9. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Berge (US Patent 4,051,565). Berge discloses the use of a relatively friction-free material for transporting patients such as a woven nylon material (column 3, lines 38-40). It is generally well known in the art that a relatively friction-free material will have a coefficient of static friction substantially the same as its coefficient of dynamic friction that is less than 0.4.

10. Claims 1, 2, 4, 6, 12, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Garner (US Patent 5,329,655).

11. Regarding claims 1, 2, 4, 6, and 12, Garner discloses a medical protection sheeting (15) formed from a low frictional woven polyester material (column 3, lines 66-67; column 4, lines 15-22). It is generally well known in the art that a low frictional material will have a coefficient of static friction substantially the same as its coefficient of dynamic friction that is less than 0.4. Further, it is well known that woven polyester material may have a linear density between 400

and 1,000 decitex and a weight between 50 and 200 g/m² as evidenced by DeBenedictis et al. (US Patent Pub. 2006/0252322) (Abstract).

12. Regarding claims 23-25, Garner discloses a medical protection sheeting (15) capable of covering and coming into contact with human skin, the sheeting material formed from a low frictional woven polyester material (Figs. 1-2; column 3, lines 66-67; column 4, lines 15-22). It is generally well known in the art that a low frictional material may have a coefficient of friction less than 0.4 and the coefficient of static friction within twenty percent of its coefficient of dynamic friction. Further, it is well known that woven polyester material may have a linear density between 400 and 1,000 decitex and a weight between 50 and 200 g/m² as evidenced by DeBenedictis et al. (US Patent Pub. 2006/0252322) (Abstract).

13. Regarding claim 26, Garner discloses method of reducing risk of damage to skin of patients in areas where skin is subject to pressure comprising the steps of providing a medical protection sheeting (15) fabricated from a woven polyester material having a low coefficient of friction and covering a patient's skin with the medical protection sheeting (Figs. 1-2; column 3, lines 66-67; column 4, lines 15-22). It is generally well known in the art that a low frictional material may have a coefficient of friction less than 0.4 and the coefficient of static friction within twenty percent of its coefficient of dynamic friction. Further, it is well known that woven polyester material may have a linear density between 400 and 1,000 decitex and a weight between 50 and 200 g/m² as evidenced by DeBenedictis et al. (US Patent Pub. 2006/0252322) (Abstract).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3772

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berge (US Patent 4,051,565). Berge discloses the invention substantially as claimed, as described above. Furthermore, Applicant has disclosed that commercially available nylons DuPont 470T743, 350T749, and 98Wext/4 have suitable properties for the intended use but Applicant has not altered the properties to produce any unexpected result (pages 2-3 of Specification). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to use a low-frictional nylon, such as made by DuPont, for a medical sheeting device as taught by Berge since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

16. Claims 1, 2, 4, 6, 12, and 23-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Garner (US Patent 5,329,655). Garner discloses the invention substantially as claimed, as described above. Furthermore, Applicant has disclosed that commercially available nylons DuPont 470T743, 350T749, and 98Wext/4 have suitable properties for the intended use but Applicant has not altered the properties to produce any unexpected result (pages 2-3 of Specification). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to use a low-frictional nylon, such as made by DuPont, for a medical sheeting device as taught by Garner since it has been held to be within the general skill of a worker in the art to select a

known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

17. Claims 4-7, 12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berge as applied to claims 1 and 2 above in view of DeBenedictis et al. (US Patent Pub. 2006/0252322).

18. Regarding claims 4, 12, and 14, Berge discloses the invention substantially as claimed, as described above, but fails to teach that the linear density of the material is between 40 and 1,000 decitex and is about 470 decitex. DeBenedictis discloses that the commercially available nylon yarn DuPont T743, which has also been disclosed by Applicant as a suitable material, has a linear density of 467 decitex (Table 2).

19. Regarding claims 5 and 7, Berge fails to teach that the material has a linear density of 350 decitex and a weight of 180 g/m². As disclosed by Applicant, commercially available DuPont T749 has a linear density of 350 decitex and a weight of 180 g/m² (pages 2-3 of Specification).

20. Regarding claim 6, Berge fails to teach that the material has a weight between 200 and 50 g/m². DeBenedictis discloses that the weight of DuPont 743 is 183 g/m² (page 3, ¶ 43).

21. Regarding claim 15, Berge fails to teach that the material has a linear density of about 50 decitex. As disclosed by Applicant, commercially available DuPont 98Wext/4 has a linear density of 50 decitex.

22. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garner as applied to claim 1 above in view of Kuehnreich (US Patent 5,176,624). Garner discloses the invention substantially as claimed, as described above, but fails to teach that the material is

formed as a boot without a toe. Kuehnreich discloses a shoe bandage adapted to be worn over a foot bandage, foot injuries, or foot wounds that may be formed with a cutout (23) for the toes (Fig. 5; Abstract; column 4, lines 40-42). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to use a medical material as disclosed in Garner in the form of a boot as taught by Kuehnreich for the care of foot related injuries.

23. Claims 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuehnreich (US Patent 5,176,624) in view of Holt et al. (US Patent 5,778,565).

24. Regarding claims 16 and 21, Kuehnreich discloses a shoe bandage adapted to be worn over a foot bandage, foot injuries, or foot wounds, comprising a housing (1) for enveloping a foot; a first and second end located about the housing such that the first end is enclosed forming a toe and a second end includes an opening for receiving a foot; an external seam securing the housing of the boot from the first end to the second end; a slice (4) extending from the opening at the second end to a midsection of the boot; a plurality of straps (8, 9) encompassing the slice for the substantially closing and securing the slice about a foot (Figs. 3-7; column 3, line 54 – column 4, line 24). However, Kuehnreich fails to teach a collar surrounding the opening at the second end.

Holt discloses an orthopedic shoe (10) made of a woven material comprising a housing (14) and a collar (28a/28b) surrounding an opening at a second end for receiving a foot of a user (Figs. 1-2; column 2, lines 51-57; column 4, lines 50-52). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the shoe bandage taught by Kuehnreich to further comprise a collar as taught by Holt for the purposes of securing the shoe around the user's ankle. However, the combination of Kuehnreich and Holt fails to teach that the housing is made from a low frictional material with a coefficient of static

friction substantially the same as its coefficient of dynamic friction. At the time the invention was made, it would have been obvious to one having ordinary skill in the art to make the shoe bandage taught by the combination of Kuehnreich and Holt such that the housing comprises of a low frictional material such as a nylon material since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416

25. Regarding claim 17, Kuehnreich discloses that the shoe bandage can be formed with a cutout (23) for the toes (column 4, lines 40-42).

26. Regarding claims 18-20 and 22, linear density, coefficient of friction, and weight are inherent properties of a given material. Applicant has disclosed that commercially available nylons DuPont T743, T749, and 98Wext/4 have suitable properties for the intended use (pages 2-3 of Specification). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to make the shoe bandage taught by the combination of Kuehnreich and Holt such that the housing comprises of a low frictional material such as a nylon material since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416

Response to Arguments

27. Applicant's arguments filed July 9, 2008 have been fully considered but they are not persuasive.

28. In response to Applicant's argument that Berge teaches that the material or fabric used is desirably made from high friction material, the examiner notes that layer (20) of the medical

sheeting was not relied upon in the above rejection but rather the friction-free material of layer (22). Applicant's claims do not preclude other materials from being part of the medical sheeting.

29. In response to Applicant's argument that Berge results in a negative teaching because the high frictional material contacts the patient's skin, it is noted that the features upon which Applicant relies (i.e., material contacting the patient's skin) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

30. In response to Applicant's argument that Berge and DeBenedictis are nonanalogous art, it has been held that a prior art reference must either be in the field of Applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, DeBenedictis was merely relied on to teach a known material with the desired properties.

31. While Applicant's declaration filed March 27, 2009 have been considered, they do not provide indisputable proof that the selected DuPont (470T743, 350T749, and 98Wext/4) materials were commercially available prior to Applicant's priority date and are beneficial over common material for medical protection sheeting.

32. In response to Applicant's assertion that the selected DuPont materials were not commercially known at the time of Applicant's invention, it is noted that Applicant has not provided any conclusive documentation. While Dr. Barnes states that the "DuPont products were not commercially available *in products related to the Pike invention* prior to the Priority Date", there is no indication that the DuPont materials were not commercially available in any products. Upon further searching, it was found that both 470T743 and 350T749 were

commercially available in the area of airbags (see attached DuPont Airbag Fibers). Therefore, the materials were on the market and available for commercial use.

33. Applicant's statement that he is not aware of any known documentation regarding Applicant's and/or DuPont's common testing outside of the oral and confidential agreement with Dr. Barnes does not sufficiently provided *any and all* known documentation of at least Applicant's testing. Applicant's specification only provided example of testing 470T743 against linen (pages 3-4); however, Applicant has not provided detailed description of what each test included or testing of any of the other DuPont materials or any other commonly used material in medical protection sheeting (i.e., polyester, rayon, etc.). Further, there is no analysis of the test results to show why the DuPont materials are preferable over any other material.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI J. NICHOLSON whose telephone number is 571-270-3821. The examiner can normally be reached on Monday - Thursday, 8am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 3772

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJN

/Keri J. Nicholson/

Examiner, Art Unit 3772

4/9/2009

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772